REMARKS

In the present Amendment, none of the claims have been cancelled. Thus, claims 2, 17-19, 22, 23, 26, 30-32 and 36 remain at issue.

A. Rejections under 35 U.S.C. §112

In the Application, Claims 32 and 36 are rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applications regard as the invention. Applicants respectfully submit that Claim 31 was meant rather than Claim 32, and thus, amendments were made to claims 31 and 36. Applicants submit that the amendments overcome the rejection of these claims.

B. Rejection Under 35 U.S.C. §103

Claims 2, 17-19, 22, 23, 26, 30-32 and 36 are rejected under 35 U.S.C. §103(a) as being unpatentable over an article by Kuhn et al in view of an article by Ripoche et al.

Kuhn et al. describe human factor H-like protein (FHL-1) is composed of seven repetitive elements (SCR) that are identical in sequence to the seven N-terminal SCR of complement factor H. Kuhn et al. "show that the FHL-1 protein has decay acceleration activity in that it can dissociate C3/C5 convertases bound to the surface of sheep red blood cells." While the same activity was also determined for factor H, Kuhn et al. teach that factor H was more efficient in decay acceleration than the FHL-1. Kuhn et al. demonstrated that FHL-1 and factor H have "identical and overlapping regulatory functions in the complement systems and that the domain required for this activity is located in the overlapping region of both proteins within the N-terminal four SCR." As noted in the Office Action, Kuhn et al. does not teach a molecule consisting of complement control modules, i.e., SCR 1-4 of complement factor H.

Ripoche et al. teaches the entire full length sequence of factor H in Figure 2 and arranges the sequence into twenty homologous units in Figures 3 and 4. Ripoche et al. teach factor H coupled to a chromatographic medium, i.e., an artificial membrane. However, the focus of Ripoche et al. is on the entire sequence of factor H, not on discrete constituents.

In the present invention, Applicants have found and demonstrated that complement control modules 1-4, 1-5 and 1-6 of the factor H protein are surprisingly and unexpectedly potent in regulating the complement activation pathway. It is not suggested in either reference, alone or in combination, that the complement control modules of Applicants' invention are even identified, or that the truncated protein modules would provide the enhanced cofactor activity as demonstrated by Applicants.

For instance, neither reference, alone or in combination, teach or suggest which amino acids correspond to complement control protein modules (1-4, 1-5 and 1-6) or even what those protein modules may be. For instance, Kuhn et al. state that SCRs 1-4, 1-5 and 1-6 are in the 7 N-terminal SCR of complement factor H; however Kuhn et al. do not state between which amino acid residues each SCR lies. Furthermore, it is noted above that Kuhn et al. do not teach a molecule consisting of complement control modules. As stated above, Ripoche et al. provides the full length sequence of factor H, and arranges the sequence in twenty homologous units in Figures 3 and 4. However, Ripoche et al. does not at any point say which sequences are the 7-N terminal SCR of factor H. Moreover, it might be assumed that each of the twenty homologous units of Ripoche et al. comprises an SCR, and thus SCRs 1-4 would comprise the first four lines of the sequence shown in Figure 3 of Ripoche et al.. However, SEQ ID NO. 9 of the present application actually ends about one third of the way along line number 4 of the Ripoche et al.

sequence, and thus SCR1-4 of the present invention is actually shorter than would be assumed from Ripoche et al. The same can be said for SEQ ID NO. 10, corresponding to SCR 1-5, which finishes about one third of the way long line number 5 of the Ripoche et al. sequence, and SEQ ID No. 11, corresponding to SCR 1-6, which ends just under half way along line 6 of the Ripoche et al. sequence. Thus, the references, alone or in combination, do not teach or suggest the sequences of the complement control protein modules of the present invention.

Furthermore, Kuhn et al. state that factor H was more efficient in decay acceleration than human factor H-like protein (FHL-1). Ripoche et al. is directed to the entire factor H sequence. Thus, while it may appear to be proper to combine the two references, because both discuss factor H, this is where the similarity to Applicants' invention ends. The statement is made in the Office Action that "one of ordinary skill in the art would be motivated to do this [combine Kuhn et al. with Ripoche et al.] in order to make a protein that could more efficiently effect decay acceleration at a lower concentration as taught by Kuhn et al. and . . . wherein coupling to an artificial membrane is effected . . . as taught by Ripoche et al." However, Kuhn et al. teach that it is factor H, not a truncated recombinant human factor H, as taught and claimed by Applicants, that was more efficient in decay acceleration. Specifically, Kuhn et al. state "[h]owever, despite this common function, a marked difference was observed in the activity of these two related plasma proteins. Compared to FHL-1, FH is about 100-fold more efficient in protecting SRBC [sheep red blood cells] from lysis by the alternative pathway." (Kuhn et al. page 2383, last paragraph). Again, Ripoche et al. teach the entire factor H, not the "truncated recombinant human factor H protein SCR 1-4 (a protein of 207aa and 23kDa) as SEQ ID NO:9," stated on page 15, lines 4-5 of Applicants' specification. Thus, the fact that Applicants' truncated

recombinant factor H is approximately 10-100 fold more potent than the serum protein FHp155, and that the potency can be found particularly in constructs representing control protein modules 1-6, 1-5 and 1-4, further distinguishes Applicants' invention from Kuhn et al. and Ripoche et al. alone or in combination. The conclusion is that neither Kuhn et al. nor Ripoche et al. alone or in combination teach a molecule consisting of complement control modules 1-4, 1-5 and 1-6 of the present invention.

In view of the above Amendments and remarks, Applicants respectfully submit that claims 2, 17-19, 22, 23, 26, 30-32 and 36 are now in condition for allowance, and such action is respectfully requested.

Respectfully submitted,

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By: Monique A. Morneault

Monique A. Morneault, Reg. No. 37,893
Wallenstein Wagner & Rockey, Ltd.
311 South Wacker Drive, 53rd Floor
Chicago, Illinois 60606-6630
(312) 554-3300
Attorneys for Applicants

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Natha Conerly

Natha Conerly

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